

DETAILED ACTION

Applicant's election of Group I, claims 2, 4, 5-9 and specie election of 131-I-CC49 on the reply filed on 12/20/2007 is acknowledged. Because Applicant did not distinctly and specifically point out supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.02(a)).

Per Applicant's request on the interview conducted on 02/05/08, Examiner confirms Applicants misspelled nomenclature in claims 2, 4, 5-9 and will examine the claims based on the structure provided on page 2 of the specification.

Claims 3, 7-8 and 10-17 have been cancelled, claim 2 has been amended and no claims have been added.

Claims 2, 4-6, 9 are presently under examination and are the subject of this Office Action.

Information Disclosure Statement

The information disclosure statement filed on 11/28/2006 has been received. Documents that were not provided were not considered during the examination process.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4-6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Divgi et al (Journal of Nuclear Medicine, Vol.36. No. 4, 1995) and Sorokin (Clinical Journal of Oncology Nursing, Vol. 6. No. 1, 2002).

Divgi et al. teaches of a Phase I study with escalating doses of ¹³¹I-CC49 in patients with advanced colorectal cancer expressing the TAG-72 antigen to determine the dose-limiting toxicity and therapeutic efficacy (see abstract). All patient had excellent targeting of radioactivity to known tumor sites (see abstract).

Sorokin teaches of radioimmunotherapy which combines a radioactive isotopes such as Iodine-131 or Yttrium 90 with a MOAB (page 20, column 2, under Radioimmunotherapy). Once at the tumor site the radioisotope targets radiation to that area (page 20, column 2, under

Radioimmunotherapy). The author further teaches that STI 271 (preclinical trial name for the elected compound) is used to selectively inhibit the proliferation of BCR-ABL tyrosine kinase expressing cells (page 21, column 1, under STI 571). Further it is taught that patients were treated on an outpatient basis with oral STI 571 in doses ranging from 300-600 mg daily. Median duration of therapy was 68 days (page 21, column 2, under STI 271).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to do so because both are directed to the treatment of tumors. Moreover, combining agents which are known to be useful as anti-cancer agents individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Since it is prima facie obvious to combine two agents each of which is taught by the prior art to be useful for the same purpose, the idea of combining STI 571 and 131 I-CC49 flows logically from having been individually taught in the prior art.

With respect to claim 5 and 9 the determination of mode of administration and pharmaceutically acceptable salts, that have the optimum therapeutic index are well within the level of one having ordinary skill in the art. Accordingly, the artisan would have been motivated to determine optimum pharmaceutically acceptable salts in order to get maximum effects of the active agent. Moreover, a recitation of the intended use of the claimed invention would result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claims. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re*

Casey, 152 USPQ 235 (CCPA 1067) and *In re Otto* 136 USPQ 458, 459 (CCPA 1963).

Additionally, Suggestion, teaching or motivation does not have to be explicitly and “may be found in any number of sources, including common knowledge, the prior art as a whole or the nature of the problem itself”, citing *Dystar Textilfarben GMBH v. C.H. Patrick Ci.*, 464 F.3d 1356 (Fed. Cir. 2006).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1614

AP

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614